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Brief Report

Managing gestational diabetes mellitus using a smartphone application with artificial intelligence (SineDie) during the COVID-19 pandemic: Much more than just telemedicine

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ABSTRACT

We describe our experience in the remote management of women with gestational diabetes mellitus during the COVID-19 pandemic. We used a mobile phone application with artificial intelligence that automatically classifies and analyses the data (ketonuria, diet transgressions, and blood glucose values), making adjustment recommendations regarding the diet or insulin treatment.

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Gestational diabetes mellitus (GDM) is a frequent disease and if the glucose control is inadequate, it increases the risk of perinatal complications. Its management involves frequent hospital visits to check self-monitoring data (glycemia levels,

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Table 1 – Summary of Sinedie app data received from GDM women.

Start date	Id	Number of days using the app[a]	Total BG uploaded (BG/day)	Glucose levels[b] FBG / 1hBG		App therapy change proposals		
				First 3 days	Last 3 days	Diet changes	Start insulin therapy	Adjust insulin
31/03	1	43.3	168 (3.9)	84 / 115	87 / 103	1	–	–
06/04	2	3.5	23 (6.5)	103 / 125	–	–	–	–
08/04	3	36.6	147 (4.0)	82 / 119	73 / 104	–	1	–
08/04	4	36.6	146 (4.0)	94 / 123	96 / 120	–	1	4
08/04	5	12.0	52 (4.3)	85 / 130	92 / 134	–	1	–
08/04	6	37.1	164 (4.4)	84 / 129	84 / 112	–	1	2
08/04	7	36.0	144 (4.0)	89 / 132	91 / 131	–	1	6
08/04	8	37.0	151 (4.1)	93 / 136	96 / 141	–	1	6
09/04	9	22.2	89 (4.0)	83 / 126	92 / 120	–	–	–
16/04	10	29.0	115 (4.0)	87 / 132	93 / 118	1	1	–
22/04	11	22.6	91 (4.0)	85 / 127	93 / 126	2	1	–
28/04	12	16.5	36 (2.2)	83 / 115	78 / 117	–	–	–
28/04	13	16.5	71 (4.3)	97 / 124	95 / 138	–	1	1
29/04	14	15.4	71 (4.6)	92 / 128	89 / 122	–	1	–
29/04	15	4.6	17 (3.7)	96 / 122	–	–	1	–
29/04	16	15.5	55 (3.6)	86 / 123	89 / 120	1	–	–
06/05	17	8.6	36 (4.2)	71 / 128	71 / 111	–	–	–
06/05	18	8.6	37 (4.3)	91 / 122	86 / 124	–	1	–
12/05	19	2.5	12 (4.7)	82 / 96	–	–	–	–
12/05	20	2.1	10 (4.8)	64 / 104	–	–	–	–

BG, blood glucose measurement; FBG, fasting blood glucose; 1hBG, 1-h postprandial blood glucose

[a] From 31 March to 14 May 2020

[b] Mean glucose levels (mg/dL) during the first 3 full days vs. last 3 full days. If there is not enough data, the field is blank.

fasting ketonuria, adherence to the diet). Throughout the follow-up clinicians decide whether any treatment adjustment is necessary.

Telemedicine is commonly defined as health services provided by healthcare professionals using remote communication technologies and it includes a wide selection of modalities. In the field of GDM, telemedicine can reduce the need for hospital outpatient visits, allowing remote patient monitoring and requiring face-to-face visits only if insulin treatment is initiated [1]. A recent *meta*-analysis of 32 randomized controlled trials (5108 patients) showed that compared to standard care, the use of telemedicine could improve glycemic levels of women with GDM more effectively and reduce the risk of pregnancy complications [2].

Some limitations of telemedicine include usability, real-time feedback, a more significant workload (as it generates a greater amount of data), and decision-making capabilities (both for patients and clinicians). Decision support tools integrated into telemedicine systems can help clinicians with the analysis of the information generated. In 2016 we developed a web-based telemedicine platform (SineDie) that operated as a clinical decision support system designed to manage GDM treatment. SineDie automatically prescribed diet therapy modifications, identified the need for insulin treatment and proposed insulin dose changes to doctors. We performed a randomized clinical trial that showed an 88.6% reduction of the face-to-face visits and a 27.4% reduction of the time devoted by clinicians to patients' evaluation. The system detected all situations that required therapy adjustment, generating safe recommendations [3]. However, when using the web-based system some patients experienced downloading problems with the glucose meter, patients had to be trained very well before using it and they needed access to the computer for data registration. Lately, we have developed the mobile version (only available on Android smartphones) to make the tool more user-friendly and easy to use, and we are about to start the clinical study.

The current COVID-19 pandemic has brought telemedicine in the spotlight [4,5]. In such an exceptional situation, we started using the SineDie app for the remote evaluation of all GDM patients visited in our Endocrinology department (after they signed an informed consent form). Women with GDM using the SineDie app follow the same self-monitoring guidelines as in standard care, but instead of going to the weekly outpatient visit, they send their data to the app. Their glycemia data is uploaded through Bluetooth connectivity from the glucose meter while ketonuria, lack of compliance to dietary, and insulin treatment can be entered manually. The system automatically analyzes the data and the patients receive instant feedback after each data upload: Nutritional advice about carbohydrates intakes is prescribed to the patient in the therapy scenario of the app and if insulin treatment is needed, the physician is notified. When no data is received during the last three days, the app sends a reminder to insist on the importance of frequent data transmission.

The clinicians can access the professional SineDie app as many times as needed and can contact by telephone, send a text message with the app, or schedule a face-to-face visit if necessary. The app shows the patients' current metabolic condition with a code of colors (normal, altered or significantly altered) and points out the patients with treatment proposals awaiting for validation. When a patient is selected, the professional has access to all the data registered, treatment details, and proposals about treatment changes. When the system generates a recommendation about insulin therapy, a proposal of daily insulin prescription is generated: amount and type of insulin, and moment of administration. The clinicians can accept, modify, or reject the proposals. Initiation of insulin prescription requires to schedule a face-to-face visit to give advice about insulin therapy management, while subsequent modifications are managed through the app after approval of the clinician. When a treatment change is made, it is automatically notified to the patient with a pop-up message.

From 31 March to 14 May 2020, 20 pregnant women with GDM started using the Sinedie app. They were followed during a median of 16.5 days (8.6–36.2; Q25-Q75). Mean ± SD number of daily glucose measurements were 4.2 ± 0.8 and data transfer frequency was 0.9 ± 0.2 upload/24 h (342 uploads in 7 weeks). Mean ± SD fasting blood glucose and 1-hour postprandial blood glucose were 89 ± 12 mg/dL and 122 ± 23 mg/dL (breakfast), 123 ± 21 mg/dL (lunch), 122 ± 22 mg/dL (dinner). Table 1 includes mean of fasting blood glucose and 1-hour postprandial the first three days using the app and the last three days, for patients followed for more than 8 days. During the follow-up, the system generated diet adjustments in 20% of the patients, 12 patients initiated insulin treatment and 41.7% of them required therapy adjustment afterwards (Table 1). 45.2% of insulin proposals generated by the system were accepted, 29.0% postponed and 25.8% rejected. Before publication, we reviewed maternal and neonatal outcomes: 18 women gave birth at a median of 39 weeks of gestation (38–40; Q25-Q75). Two women had planned caesarean section delivery, one for breech presentation and the other due to intrauterine growth restriction (IUGR). Four women had c-section delivery after failure of labor induction. None had preeclampsia. None of the newborns were large for gestational age (median percentile weight was 42 [32.5–58; Q25-Q75]. Newborns did not present hypoglycemia however, six of them had jaundice and three of them were admitted to neonatal intensive care unit due to preterm birth (IUGR in a twin pregnancy and a premature rupture of membranes).

Currently, we might have to wait a long time before the routine outpatient clinic follow-up is restored. We must adapt to the new situation and leverage the potential of telemedicine resources. The use of telemedicine in the usual care entails a paradigm shift and its use could reduce the impact of a pandemic to healthcare. SineDie app may be an excellent tool to prevent unnecessary hospital visits while keeping the best quality healthcare and reducing clinicians' workload for GDM management.

Declaration of Competing Interest

Funding

Author Contributions

L.A. made clinical visits where GDM patients were taught about Sinedie app and wrote the manuscript. M.R. contributed to the development of the Sinedie app and critically revised the manuscript. I.C. made critical revisions. G.G-S, P. M−R and M.E.H contributed to the development of the Sinedie app, analyzed the data and revised the document. M.R. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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